Declaration of confidentiality and non-disclosure

Assessment of health and environmental risk by use of drugs for animal/ human clinical trials, which contains or consists of GMO

Project: Assessments of health and environmental risk by use of drugs for animal and human clinical trials, which contains or consists of GMO

Project reference number/archive number: xxxxx/xxxxxx

Background

Drugs containing or consisting of genetically modified organisms (GMO) may be used in medical treatment of both humans and animals. The Norwegian Environment Agency is responsible authority for the environmental risk assessment under the Gene Technology Act by deliberate use, such as clinical trials in Norway.

Norway is affiliated with the EU's common system of approval for the commercial release of GMO into the environment through Directive 2001/18 / EC (Directive of deliberate release). The Directive is through the Gene Technology Act implemented in Norwegian law.

The GMO, which is to be tested as a medicinal product for humans for research purpose, will require an approval under the Gene Technology Act in Norway. There is not a common procedure for approval of deliberate release under regulations for deliberate release in EU. For GMOs to be released for research purposes (trial outcome, such as clinical trials), application for approval is sent directly to competent authorities in the countries where the trial will be conducted, and an eventual approval will apply only for this country.

HAVING REGARD TO

- Article 3 (11) of the Norwegian Gene Technology Act (Act No. 38 of April 2, 1993 relating to the Production and Use of Genetically Modified Organisms, etc.) and Regulations relating to impact assessment pursuant to the Gene Technology Act;

- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms

The undersigned, acting as a representative for the Risk Assessment body undertaking the assessments of health and environmental risk by use of drugs for human clinical trials, which contains or consists of GMO on behalf of the Competent Authority, as identified above, hereby declares to:

Keep strictly confidential all information received from the Competent Authority and from the Norwegian Medicines Agency in relation to the above mentioned assessments of health and environmental risk by use of drugs for human clinical trials, which contains or consists of GMO which includes, but is not limited to, the complete dossier including all assessment reports and clinical studies relating to the product, and the name of the applicant and of the product.

The undersigned acknowledges that he/she is bound not to disclose any of the aforementioned information to any third party or the public during the evaluation of the clinical trials, including the above mentioned risk assessment.

This declaration of confidentiality and non-disclosure shall be applicable as of the date of signature by the representative of the Norwegian Scientific Committee of Food and Environment, for any information provided to the undersigned within the context of any current and any future assessments of clinical trials on medical products for human and animal use, which contains or consists of GMO.

Name of the GMO Competent Authority and Member State:

The Norwegian Environment Agency
PO Box 5672 Torgarden
N-7485 Trondheim
Norway

Name of the Risk Assessment Body undertaking the risk assessments on behalf of the Competent Authority and to which the Competent Authority sends its mandate related to the above mentioned project:

Norwegian Scientific Committee for Food and Environment,
represented by its Secretariat
PO Box 222 Skøyen
N-0213 Oslo
Norway

Name and e-mail address of the person representing the Norwegian Scientific Committee for Food and Environment in the above mentioned risk assessment project:

Ragnhild Tønnessen
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Name and signature of the person authorised to represent the Norwegian Scientific Committee for Food and Environment in the above mentioned risk assessment project:

Name: Ragnhild Tønnessen

Signed: Ragnhild Tønnessen

Date of signature: 11.12.2019